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07 December 2018

Dr Robert French
Cardiff University
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Dear Dr French

Application title:	**Trajectories of diabetes related health measures (from linked lab data) and subsequent health and educational outcomes**
CAG reference:	**18/CAG/0002**
IRAS project ID:	**230333**
REC reference:	**17/WA/0410**

Thank you for your amendment request to the above research application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether an application should be approved, and if so, any relevant conditions.

Health Research Authority decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The amendment is approved, subject to compliance with the standard conditions of support.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

Context

Purpose of Application

This application from Cardiff University set out the purpose of medical research aiming to better understand the effects of diabetes on educational outcomes. It was acknowledged that education may also have an impact on an individual's diabetes management. The applicants have an interest in how other factors influence the relationships between health and education, these include characteristics of the child (e.g. gender), their families (e.g. single parent families), and the health services they use (e.g. type of diabetes clinic). The project aims to use linked health and education records to quantify the associations between differences in levels of HbA1c (an indicator of longer-term blood glucose levels) and educational outcomes.

The application involves the disclosure of confidential patient information from both the National Diabetes Audit (Adults – England) and National Diabetes Audit (Adults – Wales) (held by NHS Digital) and the National Paediatrics Diabetes Audit (held by the Royal College of Paediatrics and Child Health) to NHS Wales Informatics Services (NWIS). Data will also be released from the Higher Education Statistics Agency (HESA) dataset to NWIS; however, this is out of the CAG's remit as it is not confidential patient information. Corresponding clinical data will be released direct to the Secure Anonymised Information Linkage databank (SAIL), which will then be linked with psedonymised demographic data.

The applicants clarified that HESA are providing all of the additional education data – for students in England and Wales at University plus school education data for students from English schools. The school education data for pupils from Wales is already provided by Welsh Government routinely into SAIL where is it is available in psuedonymised format for linkage to the new datasets.

The legal basis for the collection of National Diabetes Audit (England) is by Directions, National Diabetes Audit (Wales) the legal basis is "section 251" (Reference: 17/CAG/0124) and for the National Paediatric Diabetes Audit the legal basis is "section 251" (Reference: ECC 2-03(c)/2012).

A recommendation for class 1, 4 and 6 support was requested to cover activities as described in the application.

Confidential Patient Information Requested

Cohort

All birth cohorts between 1983 and 2013 within England and Wales, for whom diabetes audit data (NPDA and NDA) from 2003 to 2018 and education data from 2003 to 2018 will be requested. It is anticipated that there will be 17,195 patients included within the project.

The following items of confidential patient information are required for the purposes defined:

- NHS number – used to create anonymised linkage field,
- Date of birth – used to create anonymised linkage field, validation and translated for analysis (week of birth),
- Gender – validation and analysis,

- Postcode – validation and translated to LSOA for analysis.

Wider clinical information will be provided from the diabetes audits for inclusion in the analysis dataset.

Amendment request

The amendment requests the inclusion of an additional data item, Patient Name, from the data released by the National Diabetes Audits, in order to facilitate linkage with the wider data sources in the study.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair's Action. It was recognised that project proposed linkage with educational data. As educational data did not include NHS Number, the applicant had stated that the quality of data linkage would be increased if patient name was included within the dataset disclosed from the national diabetes audits.

In reviewing the request, the CAG agreed that the amendment appeared reasonable and agreed that the additional item of confidential patient information would improve linkage with wider datasets. The applicant had also updated the patient notification materials as part of the amendment submission, which reflected the inclusion of this additional data item.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 06/11/2018**).
2. Security Assurance Arrangements – **NWIS have provided a CPIP (Caldicott: Principles into Practice) report showing a 94% satisfactory assessment rate)**.

Reviewed documents

Document	*Version*	*Date*
Amendment request form		08 November 2018
REC Favourable Opinion		08 November 2018
Patient Notification Materials (Website Text)	2	08 November 2018

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

Yours sincerely

Miss Kathryn Murray
Senior Confidentiality Advisor

On behalf of the Health Research Authority

Email: HRA.CAG@nhs.net

Enclosures:	*List of members who considered application* *Standard conditions of approval*
Copy to:	penny.beresford@wales.nhs.uk hra.amendment@nhs.net data.applications@nhsdigital.nhs.uk Darren.Lloyd@wales.nhs.uk

Health Research Authority

Standard conditions of support

Support to process confidential patient information without consent, given by the Health Research Authority, is subject to the following standard conditions of support.

The applicant and those processing the information will ensure that:

1. The specified confidential patient information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant, in addition to other national guidance.

4. All staff with access to confidential patient information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to confidential patient information have received appropriate ongoing training to ensure they are aware of their responsibilities.

6. Activities remain consistent with the General Data Protection Regulation and Data Protection Act 2018.

7. Audit of data processing by a designated agent is facilitated and supported.

8. The wishes of patients who have withheld or withdrawn their consent are respected.

9. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be approved via formal amendment prior to changes coming into effect.

10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.

11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken / to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.